**AFFIDAVIT OF SPECIAL AGENT BENEDICT CELSO,
UNITED STATES FOOD AND DRUG ADMINISTRATION,
OFFICE OF CRIMINAL INVESTIGATIONS,
IN SUPPORT OF A CRIMINAL COMPLAINT AND ARREST WARRANT**

I, Benedict Celso, depose and say:

I. INTRODUCTION

1. I am a Special Agent with the United States Food and Drug Administration ("FDA"), Office of Criminal Investigations ("FDA/OCI"), and have been so employed since February 2011. I previously was employed as a Special Agent with the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG"), for approximately eight years. I am a graduate of the Criminal Investigator Training Program of the Federal Law Enforcement Training Center in Glynco, Georgia, and have received extensive training in criminal investigation procedures and criminal law.

2. As an FDA/OCI Special Agent, I currently am assigned to the Boston Resident Office. I am responsible for conducting criminal investigations involving violations of the Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 et seq., ("FDCA") and other federal statutes enforced by FDA. I am a law enforcement officer of the United States within the meaning of 18 U.S.C. § 2510(7), and am empowered by law to conduct investigations and to make arrests for offenses enumerated in 18 U.S.C. § 2516, including mail fraud. During my tenure as a Special Agent with FDA/OCI, I have conducted investigations of several types of criminal activity, including health care fraud, and the shipment in interstate commerce of misbranded drugs.

3. This affidavit is in support of a criminal complaint charging Defendant **GLENN A. CHIN ("CHIN")**, born on XXXXX XX, XXXX, and residing at XXX XXXXXXXX XXXXXX, Canton, Massachusetts, with devising and intending to devise a scheme to defraud or to obtain money by means of materially false or fraudulent pretenses, representations, or promises; and knowingly causing medication labeled as injectable, meaning that the medication was sterile and fit for human use, to be delivered by a private commercial interstate carrier according to the direction thereon for the purpose of executing such scheme, in violation of Title 18, United States Code, Section 1341.

4. The information set forth in this affidavit results from, among other sources, interviews of witnesses, physical surveillance, and reviews of records and publicly-filed documents. The affidavit is based on my personal observations during the course of this investigation and on information conveyed to me by other government and law enforcement officials. Because this affidavit is submitted for the sole purpose of seeking issuance of a criminal complaint, it does not include every fact known to me concerning the investigation. Instead, I only have included those facts that I believe are needed to establish the requisite probable cause to support the criminal complaint.

II. DISCUSSION OF EVIDENCE

Through knowledge gathered during this investigation, I know the following:

A. Background of the 2012 Fungal Meningitis Outbreak

5. On September 24, 2012, the Massachusetts Board of Registration in Pharmacy (the "Board of Pharmacy") was informed by the Tennessee Department of Health ("TDH") that it was investigating an outbreak of fungal meningitis in six patients at an ambulatory surgical center. Depending on the patient, TDH believed that the onset of symptoms of the meningitis occurred between July 30, 2012 and September 18, 2012.

6. The six patients in Tennessee each had received a lumbar steroid injection of preservative-free methylprednisolone acetate 80 mg/ml. Each of the preservative-free methylprednisolone acetate injections was compounded at New England Compounding Pharmacy, Inc., doing business as New England Compounding Center (hereinafter "NECC"), in Framingham, Massachusetts. Each of the preservative-free methylprednisolone acetate injections was labeled as "injectable," meaning that it was sterile and fit for human use.

7. The Centers for Disease Control and Prevention ("CDC"), headquartered in Atlanta Georgia, confirmed fungal infections in patients treated with preservative-free methylprednisolone acetate injections from NECC. The patients received either epidural injections to treat back pain, or injections in their joints to alleviate joint pain. The most common fungus identified in these patients was *Exserohilum rostratum*, which was found in 206 patients who had been treated with the methylprednisolone acetate injections from NECC. In addition, the CDC found sixteen other varieties of fungi in thirty-seven other patients treated with the methylprednisolone acetate injections from NECC.

8. The FDA and CDC confirmed the presence of *Exserohilum rostratum* in multiple unopened vials of preservative-free methylprednisolone acetate made by NECC and obtained from both NECC's facility in Framingham and from NECC's customers around the country. Specifically, the FDA and CDC confirmed the presence of *Exserohilum rostratum* in three different lots of preservative-free methylprednisolone acetate made by NECC.

9. On September 26, 2012, NECC initiated a voluntary recall of the three contaminated lots of preservative-free methylprednisolone acetate 80 mg/ml. Investigators have learned that NECC shipped more than 17,000 vials of preservative-free methylprednisolone acetate 80 mg/ml from the three contaminated lots to more than seventy-six facilities located in twenty-three states.

10. On October 3, 2012, NECC surrendered its pharmacy license to the Board of Pharmacy and ceased its operations. On October 6, 2012, NECC expanded the recall to all products compounded at the facility due to the risk of possible contamination.

11. The CDC has reported that approximately 751 patients, living in twenty states, have been diagnosed with a fungal infection after receiving preservative-free methylprednisolone

acetate from NECC. Of those 751 patients, the CDC has reported that 64 have died.[1]

B. NECC's Operations and CHIN's Role

12. NECC is a corporation organized under the laws of the Commonwealth of Massachusetts. NECC described its business as a compounding pharmacy.

13. Based on my training and experience, I know that drug compounding is supposed to be a process by which a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient and dispensed pursuant to a valid prescription. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. I know that NECC mass produced medications at its facility and sold it to medical facilities located throughout the United States in exchange for payment. NECC shipped the medications to customers primarily by commercial interstate carrier. During the course of this investigation, law enforcement investigators have obtained from NECC copies of orders from facilities throughout the United States. In addition, law enforcement investigators have obtained from NECC copies of invoices and shipping records that show NECC sold prescription medication to more than 12,000 customers in all fifty states.

14. **CHIN** served as a supervising pharmacist of NECC's sterile clean rooms. At the time NECC closed in October 2012, **CHIN** supervised four other pharmacists and more than ten pharmacy technicians. In addition to his supervisory responsibilities, **CHIN** also compounded many of the medications sold by NECC. Specifically, **CHIN** was responsible for compounding all of the steroid stock solutions, including preservative-free methylprednisolone acetate 80 mg/ml.

C. NECC's Unsafe Production Practices

15. During the course of this investigation, I have learned of numerous unsafe practices employed by **CHIN** at NECC while producing supposedly sterile medication. These unsafe practices included improper sterilization and improper testing of supposedly sterile medication. Moreover, to conceal these unsafe practices, **CHIN** instructed pharmacy technicians to mislabel medication to indicate it was properly sterilized and tested.

D. NECC's Insanitary Conditions

16. During the course of this investigation, I also have discovered that the medication compounded by NECC was prepared, filled, and held under insanitary conditions. Specifically, NECC failed to properly clean and maintain its clean rooms. **CHIN** instructed pharmacy technicians to fraudulently complete cleaning logs at the end of each month purporting to show the rooms were properly cleaned and maintained when in fact they had not been. NECC's own

1 The CDC stopped updating its official case count as of October 23, 2013. Through knowledge gathered during this investigation, I know that the total number of infected patients has continued to increase, as has the total number of patients who have died.

internal environmental testing revealed the repeated presence of microbial isolates — bacteria and mold — within NECC's clean rooms on a weekly basis throughout 2012.

E. Shipment to Michigan Pain Specialists

17. On or about June 29, 2012, **CHIN** compounded a stock solution of preservative-free methylprednisolone acetate 80 mg/ml, which was labeled with lot number 06292012@26. **CHIN** directed and supervised pharmacy technicians to fill and label vials of that stock solution. **CHIN** directed that filled vials be sent out of the clean room for shipment to NECC customers.

18. On or about August 7, 2012, Michigan Pain Specialists PLLC ("MPS"), located in Brighton, Michigan, faxed an order to NECC for 400 5 ml vials of preservative-free methylprednisolone acetate 80 mg/ml. The order was filled with vials of preservative-free methylprednisolone acetate 80 mg/ml, which was labeled with lot number 06292012@26. Each of the vials was labeled with the abbreviation of the word "injectable" on it, meaning that the medication was sterile and fit for human use.

19. On or about August 8, 2012, NECC shipped via a commercial interstate carrier to MPS the 400 5 ml vials of preservative-free methylprednisolone acetate 80 mg/ml, each labeled as injectable.

20. Under the belief that the medication was sterile and fit for human use, MPS physicians injected the preservative-free methylprednisolone acetate 80 mg/ml into 625 patients over the next two months. The 625 patients accepted the injections into their bodies under the same belief. Following the injections, 217 MPS patients contracted fungal infections, of which fifteen died.

III. PROBABLE CAUSE

21. Based on the foregoing facts, and on my experience, training, and discussions with other individuals involved in this investigation, I believe that probable cause exists to conclude that **GLENN A. CHIN** devised and intended to devise a scheme to defraud or to obtain money by means of materially false or fraudulent pretenses, representations, or promises; and that **CHIN** knowingly caused medication labeled as injectable, meaning that the medication was sterile and fit for human use, to be delivered by a private commercial interstate carrier according to the direction thereon for the purpose of executing such scheme, in violation of Title 18, United States Code, Section 1341. Therefore, I request that a criminal complaint be issued charging **GLENN A. CHIN** accordingly, and that an arrest warrant be issued.

BENEDICT CELSO
Special Agent
U.S. Food and Drug Administration
Office of Criminal Investigations

Subscribed to and sworn before me on this 3rd day of September, 2014

JENNIFER C. BOAL
Chief Magistrate Judge
United States District Court for the District of Massachusetts